K000237

JUN 13 2000



The following information is in accordance with 21 CFR 807.92

## Submitter's Name, Address, Telephone Number, Contact Person, Preparation Date

CyberCare, Inc.
7840 Roswell Rd.
Suite 320
Atlanta, GA 30350
(770) 352-9540
Steven Ratzel

or

REH Consulting
12190 Winding Oak Trail
Alpharetta, GA 30005
(770) 772-0322
(770) 823-4295 cell
Richard E. Halbach, Ph.D.
(Regulatory Consultant to CyberCare, Inc.)

January 10, 2000

## Name of the Device and Classification Name/Number

EHC400 Desktop Patient Station (EHC400)

21 CFR 870.1130 DXN Class II
Noninvasive Blood Pressure Measuring Systems

21 CFR 870.2910 FLL Class II
Thermometer Electronic Clinical

21 CFR 870.2700 DQA Class II
Noninvasive Pulse Oximeters

## Description of the Device

The EHC400 Desktop Patient Station (EHC400) is a new monitor with the same parameters as existing legally marketed devices. The EHC400 is designed to provide monitoring of patients, at home, or other patient care environment. The system includes the following physiologic functions: Noninvasive blood pressure (NIBP), oximeter ($SpO_2$), and electronic oral temperature.

The EHC System consists of two units, a transportable EHC400 Patient Station, installed where it can be conveniently accessed by the patient, and the EHC600 Care Provider Station, installed in the office of a professional caregiver. The two terminals, modem connected by standard phone lines or other digital transmission service, provide real-time audio and video communication between the patient and the caregiver. Blood pressure, blood oxygenation saturation and pulse rate, and oral temperature are transmitted over the communication link for display on the Caregiver Terminal. The Patient Station has a touch screen display to facilitate patient interaction with the system. The Care Provider Station can function as a stand-alone database terminal to collect data from the patient for subsequent caregiver analysis.

## Substantial Equivalence

The EHC400 is substantially equivalent to aspects of the predicate systems, the BCI 9203 Advisor (K982279), the BCI 6004 Mini-Torr (K070801, K083796), and the Welch Allyn Suretemp 6004 (K964643), and has features that are equivalent to features found in the predicate devices, Alaris, LifeSigns Shuttle & Commander (K964408), American Telecare, Personal Telemedicine System (K964554), and HomMed, Monitoring System. The EHC400 and the BCI predicate devices have the same general use of vital signs data collection. The Alaris, American Telecare, and HomMed systems are intended for out-of-hospital use. These systems include cleared elements to acquire $SpO_2$, blood pressure, and oral temperature, and provide patient/caregiver communications.

There are minor differences between the EHC400 and the predicate devices. For example, with the EHC400 four vital signs are measured. Simultaneous voice, video, and data communications are possible between the patient site and the caregiver. Several of the predicates include vital signs alarm functions which are not available on the EHC400. These differences are not significant with regard to performance of the vital signs data acquisition functions. Functionality and safety of the EHC400 are substantially equivalent to the predicate devices and components.

### Intended Use

The EHC400 Desktop Patient Station is a portable patient monitoring system for intermittent use by adult patients or pediatric patients with adult supervision in the home, or in a patient care center. The system consists of a Care Provider Station (EHC600) and a Desktop Patient Station (EHC400) with two-way video, audio and data communication between the two. The EHC400 Desktop Patient Station provides the following physiologic functions:

- Noninvasive blood pressure (NIBP), provides systolic, diastolic, mean arterial pressure (mmHg)
- Oximeter, provides % oxygen saturation
- Heart Rate (BPM, function provided by oximeter)
- Electronic Thermometer, provides oral temperature ° C, °F

The device will provide NIBP for pediatric through adult patients when used with an appropriately sized blood pressure cuff. The oximetry option works with specified oximeter sensors. The thermometry section requires the use of specified oral thermometry probes and covers and provides information for patients, pediatric through adult, in the 4 second and monitor modes.

The device is not intended to be applied to the patient for long periods of time as in conventional beside monitoring applications, but for intermittent use by cooperative adult patients, or pediatric patients with adult supervision and assistance.

The EHC600 Care Provider Station provides audio/video patient contact, and patient data archival functions to the caregiver.

The indications for the EHC400 do not differ significantly from the predicate, or legally marketed devices, with the following exceptions. The device is not intended for use on neonates. It is not intended for continuous patient monitoring. Therefore, the automatic alarm limit functions available on several of the predicate devices are not included. It is not intended to be used in environments where defibrillators are expected to be used.

### Performance Data

This device uses currently available technology found in legally marketed devices. Testing, to ensure that the EHC400 would perform as intended, was conducted at two levels. Bench testing using simulators was used to test each function. Clinical testing using volunteers was used to verify performance of $SpO_2$, heart rate, NIBP, and oral temperature.

The EHC400 system meets applicable standards for performance and EMC compliance.

**Non-clinical Testing**

Commercially available simulators were used to evaluate the three functional modules within the EHC400. The same protocol was used to obtain data from three 510 (k) cleared predicate devices presently being marketed. Each predicate device tested contained a functional module equivalent to that in the EHC400 and from the same manufacturer. Test results include comparison of data between the EHC400 and the predicate device.

The average differences of all the NIBP mmHg readings were 3.87 for SYS, -0.47 for DIA, and –0.63 for MAP. The average differences of all the oximeter readings was 0.52 for % SpO2 and -0.02 BPM for heart rate. The differences for the oral temperature readings were -0.1 °F for the 4 –Second mode and -0.1 °F for the Monitor mode. This shows that the vital signs modules in the EHC400 operate the same as those in the predicate devices listed in the following table.

| EHC400 Desktop Patient Station (EHC400)Function | Predicate Unit Containing Same Functional Module |
|---|---|
| NIBP | Sims BCI Advisor Model 9203, (K982279) |
| $SpO_2$ | Sims BCI Mini-Torr Model 6004, (K970801, K983796) |
| Heart Rate | Sims BCI Mini-Torr Model 6004, (K970801, K983796) |
| Thermometer | Diatek/Welch Allyn SureTemp Model 679, (K964643) |

**Clinical Testing**

Comparative clinical testing was performed on 39 volunteer subjects under an appropriate IRB approved protocol. Differences in readings between the EHC400 and the Predicate devices listed in the above table were analyzed to determine the mean and standard deviation values. All measurements were taken with the individual seated adjacent to the Patient Terminal to simulate the normal operating environment.

The average differences of all the NIBP mmHg readings were 4.56 for SYS, -0.50 for DIA, and –0.49 for MAP. The average differences of all the oximeter readings was 0.18 for % SpO2 and 0.18 BPM for heat rate. The average differences for the oral temperature readings were 0.08 °F for the 4 –Second mode and 0.02 °F for the Monitor mode. This shows that the vital signs modules in the EHC400 operate the same as those in the predicate devices listed in the table above.

**Conclusion**

This summary of 510 (k) safety and effectiveness has been submitted in accordance with the SMDA of 1990 and 21 CFR 807.92. CyberCare concludes, based on the above referenced testing, that the device is substantially equivalent to the predicate devices as described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cybercare, Inc.
C/O Richard Halbach, Ph.D.
7840 Roswell, Suite 320
Atlanta, GA 30350

JUN 1 6 2000

Re: K000237
EHC 400 Desktop Patient Station and EHC 600 Care Provider Station
Regulatory Class: II (two)
Product Code: DXN and DQA
Dated: April 18, 2000
Received: April 19, 2000

Dear Dr. Halbach:

This letter corrects our substantially equivalent letter of June 13, 2000, regarding the 510(k) number.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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C/O Richard Halbach, Ph.D.
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Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000237

Device Name: EHC400 Desktop patient Station / EHC600 Care Provider Station

Indications for Use:

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The EHC600 Care Provider Station provides audio/video patient contact, and patient data archival functions to the caregiver.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K000237

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)